



MAY - 5 2010

Daniel J. Hulseberg
BAKER BOTTS LLP
30 Rockefeller Plaza
New York, NY 10112-4498

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,451,233

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,451,233, which claims the medical device XIENCE® V EECSS (everolimus eluting coronary stent system), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 777 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 777 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of August 4, 2009 (74 Fed. Reg. 38659). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (759 \text{ days}) + 398 \text{ days} \\ &= 777 \text{ days (2.1 years)}\end{aligned}$$

Since the regulatory review period began May 4, 2005, after the patent issued (September 19, 1995), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,451,233

Granted: September 19, 1995

Original Expiration Date¹: October 29, 2008

Applicant: Paul G. Yock

Owner of Record: Paul G. Yock

Title: Angioplasty Apparatus Facilitating Rapid Exchanges

Product Trade Name: XIENCE® V EECSS (everolimus eluting coronary stent system)

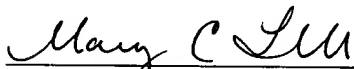
Term Extended: 777 days

Expiration Date of Extension: December 15, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: XIENCE® V EECSS
(everolimus eluting coronary stent system)
Docket No.: FDA-2008-E-0551

Attention: Beverly Friedman

¹Subject to the provisions of 35 U.S.C. § 41(b).